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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/760,046	01/12/2001	Edith Mathiowitz	BU 111	1885

7590 06/10/2002  
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EXAMINER

PULLIAM, AMY E

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 06/10/2002

9

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/760,046

Applicant(s)

MATHIOWITZ ET AL.

Examiner

Amy E Pulliam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____.  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>4</u> . | 6) <input type="checkbox"/> Other:  |

### DETAILED ACTION

Receipt is acknowledged of the Revocation and Power of Attorney, and the Election and Amendment A, all received by the Office on April 4, 2002.

Applicant's election without traverse of Group 1, claims 1-26 in Paper No. 7 is acknowledged.

#### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 17, 19, and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 17 is rejected for the phrase "phase separation technique." There is no antecedent basis for this phrase in claim 12. Did applicant intend to make claim 17 depend on claim 16? Appropriate correction is required.

Claim 19 is rejected for being unclear. It is requested that applicant more clearly define the limitations intended by this claim.

Claim 23 is rejected for the words "sufficiently" and "substantially." These two words give the claim a very broad and unclear meaning. It is unclear what it means to substantially avoid denaturing of the protein. Does this mean the protein can still be slightly denatured? Or is denaturing completely avoided. Additionally, how rapidly must the mixture be frozen to achieve

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the desired result. This is not clear from the current claim language. Appropriate correction is required

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 7-19, 23 – 26 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 5,817,343 to Burke. Burke teaches a method for forming polymer/ drug microparticles comprising the steps of (1) forming a polymer/ drug mixture comprising a polymer dissolved in an organic solvent and a suspended labile drug; (2) removing the solvent by freezing and extracting the solvent (abstract). Additionally, Burke teaches that the solvent is extracted through lyophilization (c 13, claim 21). Additionally, Burke teaches that the polymer can be a biocompatible polymer, such as poly(lactic acid), poly(lactic acid-co-glycolic acid) copolymer, poly(caprolactone), polycarbonates, polyamides, polyanhydrides, poly(amino acids), polycyanoacrylates, and polyurethanes (c 12, claim 11). Furthermore, Burke teaches that the drug can be a growth factor, a peptide, a polypeptide, or a polynucleotide (c 12, claim 3).

Claims 1-3, 7-19, 23 – 26 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 5,407,609 to Tice *et al.*. Tice *et al.* teach a method of microencapsulating an agent,

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comprising the following steps: (1) dissolving or dispersing one or more agents in a solvent containing one or more dissolved wall forming materials or excipients (a polymer), (2) dispersing the agent/ polymer solvent mixture into a processing medium (a continuous phase which is preferable saturated with a polymer solvent) to form an emulsion, and (3) transferring all of the emulsion immediately to an extraction medium to extract the solvent to form a microencapsulated product, such as microspheres or microcapsules. Additionally, Tice *et al.* list a long list of possible wall forming material at column 4, lines 3-30. Also, the reference teaches an extensive list of possible actives to be used in the formulation, including peptides (c 4, l 30-70).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burke, as discussed above, and in view of the following comments. Burke is disclosed above as teaching applicant's claimed process. Burke does not teach applicant's specific range of particle sizes, or particular ranges of solvent to non-solvent. However, it is the position of the examiner that because applicant and Burke discuss the same process, the particular size range and particular ratios are manipulatable parameters, known to the ordinary worker as the part of the process of normal optimization. One of ordinary skill in the art would have been motivated to manipulate

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the ratios and particle sizes to achieve the best result, depending on the drug to be administered. Therefore, this invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 1-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tice *et al.* , as discussed above, and in view of the following comments. Tice *et al.* are disclosed above as teaching applicant's claimed process. Tice *et al.* do not teach applicant's specific range of particle sizes, or particular ranges of solvent to non-solvent. However, it is the position of the examiner that because applicant and Tice discuss the same process, the particular size range and particular ratios are manipulatable parameters, known to the ordinary worker as the part of the process of normal optimization. One of ordinary skill in the art would have been motivated to manipulate the ratios and particle sizes to achieve the best result, depending on the drug to be administered. Therefore, this invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E Pulliam whose telephone number is 703-308-4710. The examiner can normally be reached on Mon-Thurs 7:30-5:00, Alternate Fri 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 703-308-2927. The fax phone numbers for the

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organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

aep

June 5, 2002

THURMAN K. PAGE  
SUPERVISORY PATENT EXAMINER  
/ TECHNOLOGY CENTER 1600